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| 10/047,592      | 10/23/2001  | Mark C. Noe          | PC11074A            | 5755             |

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| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/047592

Applicant(s)

Joe Ad

Examiner

J. M. Ford

Group Art Unit

1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on August 26, 2003
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1, 2, 5, 8, 11 and 14 -- 42 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 2, 5, 8, 11 and 14 -- 42 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

Office Action Summary

Applicants' response of August 26, 2003, is noted.

The claims in the application are claims 1, 2, 5, 8, 11 and 14—42.

Claim 1 is rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph. What is intended by heterocyclyl, or heteroaryl?

The claims measure the invention.

The definition for heterocyclyl and heteroaryl need to be in the claim.

The specification serves various purposes, it set forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

Heterocyclo and heteroaryl have varied definitions, as explained.

Applicants need to indicate in claim 1 what they intend by heteroaryl and heterocyclo.

The claims measure the invention, United Carbon Co. Vs. Binney & Smith Co. 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockheed Aircraft Corp. vs. United States, 193 U.S.P.Q. 449, "Claims measure the invention, and resolution of invention must be based on what is claimed".

The C.C.P.A. in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": *In re Priest*, 199 U.S.P.Q. 11, at 15.

Heteroaryl is too broadly stated in the rejected claims.

The heterocyclic expression includes adjacent O/S combinations that is unstable.

The heteroaryl expression does not tell the reader what the hetero atoms are or where they are in the ring.

Further, the USPTO only recognizes C, N, O, S, Se or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heteroaryl in the claim.

Aryl and heteroaryl are unclear as to their meaning.

The definitions refer to a heteroaryl ring, within indicating what the heterocyclic ring is, that is being claimed.

The heteroaryl term is not acceptable, as it reads on heterocyclic rings, that are not specifically set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

The heterocyclic term is not set forth in clear, specific, language. The reader must produce the heterocyclic ring, in question.

Exactly what ring is being claimed must be set forth in the claim.

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Conception of what <sup>the</sup> intended heterocyclic ring, may be, and should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at page 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic grounds for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide <sup>a</sup> clear-cut indication of the scope of the subject matter embraced by claim; this ground finds its basis in second paragraph of section 112; second is that language is so broad that it causes claim to have a potential scope of protection beyond that which is justified by specification disclosure; this ground stems from first paragraph of section 112, merits of language in claim must be tested in light of these two requirements.

The heteroaryl variable is not believed to meet the requirements of 35 U.S.C. 112, first and second paragraph.

The heteroaryl variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heterocyclic concept is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception should not be the role of the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentabilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazines, Triazines, Tetrazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced.

Conception of what the intended heterocyclic ring may be should not be left to the reader.

The claims read on rings far beyond those noted in the remarks of the response.

One needs to know, exactly, wherein the ring the hetero atoms are: 1,2 or 1,3 or 1,4 or 1,2,4 or 1,3,5, etc., as each is a different entity, with a separate search.

One must clearly know what is being claimed.

One, on reading the indication of heteroaryl term applied by applicant, has no idea where the hetero atoms are in this unknown ring.

Not all heterocyclic rings have been shown to be producible, as stable at room temperature. What is the source of the starting material? Where is the

adequate representative exemplification in the specification to support the claim language?

The heteroaryl term definition presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification? Even any combination of atoms, selected from the group consisting of O, S, or N, rests specific conception with the reader. Not a fair burden in return for applicants receiving a 17/20 year monopoly.

The possible combination of any number of hetero atoms, in any combination, in multiple size rings is quite large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible heterocyclic ring is what is needed here in the claims. It is not possible to classify and search the molecule unless one knows exactly which heterocyclic ring is being claimed.

The ultimate utility here is pharmaceutical. Declarations of unexpected results are often presented in this art. Applicant's breadth of heteroaryl produces many different heterocyclic that could easily affect results.

Applicants need to claim what they have demonstrated as a specific fact.

The heterocyclic expressions in claim 1 is not acceptable, as they do not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification

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does not include the source of the starting material for the rings, which fall within the claim language.

One must be able to tell from a simple reading of the claim what it does or does not encompass.

Why? Because that claim precludes on other from making, using, or selling that compound 17/20 years. Therefore, one must know what compound is being claimed.

Claims 2, 5, 8, 11 and 14-42 are rejected, as they are dependent on a rejected claim.

Claiming is alternative, the last line of claim 42 should be "or a pharmaceutically acceptable salt thereof".

Further, in regard to heterocyclic ring and heteroaryl in claim 1 a 35 U.S.C. 112, 1<sup>st</sup> paragraph rejection is made because applicants are claiming outside the scope of the disclosure of the invention.

Note the USPTO Classification definition.

#### HETERO RING

Denotes the presence of one or more carbon atoms covalently bonded in a closed ring with at least one atom of oxygen, nitrogen, sulfur, selenium or tellurium and having no other atoms in the ring. (Emphasis added).

Since applicants ring is no not so limited. The rings claimed by them would not be found, in a search, as the open breadth rings, of any hetero atom, would not be classified as a Hetero ring, as the USPTO only recognizes:



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c/ HETERO ATOM

Donotes oxygen, nitrogen, sulfur, selenium or tellurium atoms.

Many others recognizes other atoms as hetero."

Note Acheson, page 1 of the Introduction:

" A heterocyclic compound is one, which possesses a cyclic structure with at least two different kinds of atoms in the ring. The most common types, discussed here, contain largely carbon atoms. Nitrogen, oxygen, and sulfphur are the most common heteroatom, but many other elements, including even bromine, can also serve. The heterocyclics containing the less common atoms have been subject to much investigation in recent years but are not considered in this book."

Note Streitwiesen et al. P. 1061

" **Heterocycles** are cyclic compounds in which one or more ring atoms are not carbon (that is, hetero atoms). Although heterocyclic compounds are known that incorporate many difference elements into cyclic structures (for example, N, O, S, B, Al, Si, P, Sn, As, Cu), we shall consider only some of the more common systems in which the hetero atom is N, O, or S."

Applicants indicated their support in the remarks of the most recent amendment. Therefore, applicants claim considerably beyond their support.

J. M. Ford:jmr

October 7, 2003



JOHN M. FORD  
PRIMARY EXAMINER

*Long Art Unit 1624*